

10/553434

JCO6 Rec'd PCT/PTO 18 OCT 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

OZAKI *et al.*

Appl. No.: *To be assigned* (U.S. National
Phase of PCT/JP2004/006038; Int'l Filing
Date: April 23, 2004)

For: **MMP Expression Inhibitor**

Confirmation No.: *To be assigned*

Art Unit: *To be assigned*

Examiner: *To be assigned*

Atty. Docket: 1089.0580000/MAC/SJE

Information Disclosure Statement

Mail Stop PCT

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Forms PTO-1449 and PTO/SB/08B are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. Copies of the documents are submitted herewith.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following discussion of the relevance of the non-English language documents **AL1-AO1** and **NPL6-NPL9**.

Document **AL1**, Japanese Patent Publication No. JP 6-305955 A, is in Japanese. The relevance of document **AL1** may be determined from the unverified English translation of the specification which is attached to the Japanese language document.

Document **AM1**, Japanese Patent Publication No. JP 2004-067513 A, is in Japanese. The relevance of document **AM1** may be determined from the unverified English translation which is attached to the Japanese language document.

Document **AN1**, Japanese Patent Publication No. JP 2004-107330 A, is in Japanese. The relevance of document **AN1** may be determined from the unverified English translation which is attached to the Japanese language document.

Document **AO1**, WIPO Patent Publication No. WO 2004/056351 A1, is in Japanese. The relevance of document **AO1** may be determined from the English-language abstract located on the face page of said document and from the English language International Search Report provided with the document.

Document **NPL6**, MIYAGAWA, T., *et al.*, "Vitamin K no Kogan Sayo," *Vitamin* 74:74-76, Kyoto Nippon Bitamin Gakkai (2000), is in Japanese. The relevance of document **NPL6** may be determined from the unverified English translation which is attached to the Japanese language document.

Document **NPL7**, MIZUTA, T., *et al.*, "Vitamin K ni yoru Kansaibo Gan Saihatsu Yokusei Koka no Rinshoteki Kento," *Japanese Journal of Gastroenterology* 99 Suppl.:A192, Abstract No. 308, Rinji Zokango (Sokai) (March, 2002), is in Japanese. The relevance of document **NPL7** may be determined from the unverified English translation which is attached to the Japanese language document.

Document **NPL8**, MIZUTA, T., *et al.*, "Vitamin K Toyo ni yoru Kansaibo Gan Saihatsu Yokusei Koka no Kento (Inhibitory effect against the recurrence of hepatocellular carcinoma by vitamin K administration)," Presented at *Dai 38 Kai Nihon Kangan Kenkyukai Syorokushu (38th Annual Meeting of Liver Cancer Study Group Japan)*, p. 135, Abstract 1130, (May 2002), is in Japanese. The relevance of document **NPL8** may be determined from the unverified English translation which is attached to the Japanese language document.

Document **NPL9**, KOIKE, Y., *et al.*, "Monmyakunai Shuyo Shinjun (PVI) Yobo o Mokuteki to shita Vitamin KII Toyo ni yoru Randomized Prospective Controlled Study", *Acta Hepatologica Japonica* 43(Suppl. 1):A64, Abstract O-98, Nihon Kanzo Gakkai (2002), is in Japanese. The relevance of document **NPL9** may be determined from the unverified English translation which is attached to the Japanese language document.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

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of PCT/JPS2004/006038; Int'l Filing Date: April 23, 2004)

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed within three months of the date of entry of the national stage as set forth in 37 C.F.R. § 1.491 in an international application. No statement or fee is required. 37 C.F.R. § 1.98(b)(2).

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



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FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 1089.0580000/MAC/SJE	APPLICATION NO. To be assigned (U.S. National Phase of PCT/JP2004/006038; Int'l Filing Date: April 23, 2004
FIRST NAMED INVENTOR Iwata OZAKI		
FILING DATE Herewith		ART UNIT To be assigned

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1	JP 6-305955 A	11/01/1994	Japan			X Yes No
	AM1	JP 2004-067513 A	03/04/2004	Japan			X Yes No
	AN1	JP 2004-107330 A	04/08/2004	Japan			X Yes No
	AO1	WO 2004/056351 A1	07/08/2004	WIPO			Yes X No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

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PTO/SB/08B (07-05)

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	To be assigned (U.S. National Phase of PCT/JP2004/006038; Int'l Filing Date: April 23, 2004)
				Filing Date	Herewith
				First Named Inventor	Iwata OZAKI
				Art Unit	To be assigned
				Examiner Name	To be assigned
Sheet	1	of	1	Attorney Docket Number	1089.0580000/MAC/SJE

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published	T ²
	NPL1	International Search Report for International Application No. PCT/JP2004/006038, Japanese Patent Office, mailed August 12, 2004	
	NPL2	MIYAZAWA, K., <i>et al.</i> , "Combined treatment of leukemia cells with l-alpha, 25-dihydroxy-22-oxavitamin D3 plus vitamin K2 (VK2), results in synergistic enhancement of monocytic differentiation but also inhibition of VK2-inducing apoptosis by cytoplasmic p21CIP1," <i>Blood</i> 98 (11, pt 1): 353a, Presented at the 43rd Annual Meeting of the American Society of Hematology, Part I, Orlando, FL, American Society of Hematology (2001); printed from <i>Biol. Abstracts Inc.</i> , Accession No. 2002:186629	
	NPL3	NISHIKAWA, Y., <i>et al.</i> , "Growth Inhibition of Hepatoma Cells Induced by Vitamin K and Its Analogs," <i>J. Biol. Chem.</i> 270:28304-28310, The American Society for Biochemistry and Molecular Biology, Inc. (1995)	
	NPL4	OKAYASU, H., <i>et al.</i> , "Cytotoxic Activity of Vitamins K ₁ , K ₂ and K ₃ against Human Oral Tumor Cell Lines," <i>Anticancer Research</i> 21:2387-2392, J.G. Delinassios (2001)	
	NPL5	OTSUKA, M., <i>et al.</i> , "Inhibition of Hepatoma Cell Growth and Invasion by Vitamin K2 Administration In Vitro," Presented at the 53rd Annual Meeting on the Liver, Boston, MA, <i>Hepatology</i> 36:445A, Abstract 1130, W.B. Saunders (October, 2002)	
	NPL6	MIYAGAWA, T., <i>et al.</i> , "Vitamin K no Kogan Sayo," <i>Vitamin</i> 74:74-76, Kyoto Nippon Bitamin Gakkai (2000)	X
	NPL7	MIZUTA, T., <i>et al.</i> , "Vitamin K ni yoru Kansaibo Gan Saihatsu Yokusei Koka no Rinshoteki Kento," <i>Japanese Journal of Gastroenterology</i> 99 Suppl.:A192, Abstract No. 308, Rinji Zokango (Sokai) (March, 2002)	X
	NPL8	MIZUTA, T., <i>et al.</i> , "Vitamin K Toyo ni yoru Kansaibo Gan Saihatsu Yokusei Koka no Kento (Inhibitory effect against the recurrence of hepatocellular carcinoma by vitamin K administration)," Presented at <i>Dai 38 Kai Nihon Kangan Kenkyukai Syorokushu (38th Annual Meeting of Liver Cancer Study Group Japan)</i> , p. 135, Abstract 110, (May 2002)	X
	NPL9	KOIKE, Y., <i>et al.</i> , "Monmyakunai Shuyo Shinjun (PVI) Yobo o Mokuteki to shita Vitamin KII Toyo ni yoru Randomized Prospective Controlled Study," <i>Acta Hepatologica Japonica</i> 43(Suppl. 1):A64, Abstract O-98, Nihon Kanzo Gakkai (2002)	X
	NPL10	WU, F.Y.-H., <i>et al.</i> , "Comparison of Antitumor Activity of Vitamins K1, K2, and K3 on Human Tumor Cells by Two (MTT and SRB) Cell Viability Assays," <i>Life Sciences</i> 52:1797-1804, Pergamon Press, Ltd. (1993)	

445582_1.DOC

Examiner Signature	Date Considered
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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